Global FabTech Wheelchair (Shanghai) Co., Ltd.

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TEL: +86-21- 6763-2308 FAX: +86-21- 6763-2309

K102358

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

OCT 4 2010

Date of summary was prepared: July 30, 2010

FDA CDRH DMC

AUG 19 2010

Received

Device

Trade name: **Zip'r3 / Zip'r3 Xtra scooter**

Common name: **Electrical scooter**

Classification name: **Motorized three-wheeled vehicle**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3800**

Product Code: **INI**

Classification: **Class II**

Predicate devices

Ruike 3331 (K062676) / Shanghai Ruike Sports Goods CO., LTD.

Intend use of device

Zip'r3 and Zip'r3 Xtra scooter are intended for the indoor/outdoor electrical scooter that provide transportation for disabled or elderly persons limited to a seated position.

Device description:

The Zip'r3 and Zip'r3 Xtra scooter are the indoor/outdoor electrical scooter. The design of the scooters is basically similar to other electrical scooters that are already on the market. By providing the electrical scooter that breaks down into three manageable components (seat frame, body frame with motors and battery pack), a user can have a more practical alternative when traveling long distances by bus, train, etc.

The Zip'r3 and Zip'r3 Xtra scooters are with a **113 kg (250 lbs)** weight capacity. They are basic conventional rear wheel drive, rigid frame vehicle that are battery powered. They consist primarily of a welded steel frame, lighting system, a sealed transaxle motor **(155W, DC24V)** drive system, electromagnetic braking system, electric motor controller **(PG S-Drive 45A)** and two batteries with an **off-board** battery charger **(2A)**. They are powered by **two 12 volt lead-acid** DC batteries with **16 km (10 miles)** with **12 AH** which maximum speed upto **6.8 km/hr (4.25 mph).**

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Summary of non-clinical testing

The Zip'r3 and Zip'r3 Xtra scooter complied with the requirements of ANSI/RESNA WC/Vol.1 section 1-1998 / ISO7176-1-1999, ANSI/RESNA WC/Vol.1 section 6-1998 / ISO7176-6-2001, ANSI/RESNA WC/Vol.2 section 21-1998 / ISO7176-21-2003, IEC 61000-4-2-2001, IEC 61000-4-3-2008, CISPR 11: 2004+A2: 2006, and California Bureau of Home Furnishings 117 Flammability Standards.

Statement of substantial equivalence

The Zip'r3 and Zip'r3 Xtra scooter are substantially equivalent to the **Ruike 3331 (K062676)** manufactured by **Shanghai Ruike Sports Goods CO., LTD..**

There are minor differences in performance specifications of the electrical scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Global FabTech Wheelchair (Shanghai) Co., Ltd. concludes that, Zip'r3 and Zip'r3 Xtra scooter are substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Global FabTech Wheelchair (Shanghai) Co., Ltd.
% Ms. Junnata Chang
16F-2 (16A), No. 462, Sec. 2, ChongDe Road, Beitun District
Taichung, China (Taiwan) 406

OCT 4 2010

Re: K102358
Trade/Device Name: Zip' r3 and Zip' r3 Xtra scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 1, 2010
Received: September 1, 2010

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K102358

Device Name: **Zip'r3** and **Zip'r3 Xtra scooter**

Indications for Use:
To provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102358

(Posted November 13, 2003)